

Substitute for form 1449A/PTO

## INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 1 of 1

### Complete if Known

Application Number	10/579,251
Filing Date	October 20, 2006
First Named Inventor	Luca Gianni
Art Unit	1623
Examiner Name	Jonathan S. Lau
Attorney Docket Number	13566.105020

### NON PATENT LITERATURE DOCUMENTS

Examiner Initials *	Cite No. 1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T 2
		Alexopoulos, "Phase II study of pegylated liposomal doxorubicin (Caelyx®) and docetaxel as first-line treatment in metastatic breast cancer," Ann. Oncol., 2004, 15(6):894-5	
		Boranic et al., "A Parkinson-like Syndrome As Side Effect of Chemotherapy with Vincristine and Adriamycin in a Child With Acute Leukemia," Biomedicine, vol. 31(S), pp. 124-5, 1979	
		Gourley C. et al., "Malignant mixed Mesodermal Tumours - Biology and Clinical Aspects," European Journal of Cancer, 2002, vol. 38, no. 11, pages 1437-1446	
		Halm et al., "A phase II study of pegylated liposomal doxorubicin for treatment of advanced hepatocellular carcinoma," Ann. Oncol., 2000, 11(1):113-114	
		Hockman et al., "A phase I/II study of dose-escalated docetaxel given two weekly in combination with a fixed dose of G-CSF," European Journal of Cancer, vol. 37, page S76, Abstract 270, October 22, 2001	
		Lau et al., "A Phase I and Pharmacokinetic Study of Ecteinascidin-743 (Yondelis) in Children with Refractory Solid Tumors," Clinical Cancer Research, vol. 11, pp. 672-677, Jan. 15, 2005	
		Puchalski et al., "Pharmacokinetics of Ecteinascidin 743 Administered as a 24-h Continuous Intravenous Infusion to Adult Patients with Soft Tissue Sarcomas: associations with Clinical Characteristics, Pathophysiological Variables and Toxicity," Cancer Chemotherapy and Pharmacology, 2002, vol. 50, no. 4, pages 309-319	
		Sarosy et al., "Phase I Study of $\alpha$ 2-interferon plus Doxorubicin in Patients with Solid Tumors," Cancer Research, vol. 46, pp. 5368-5371, 1986	
		Tyelves et al., "Phase I and pharmacokinetic study of Yondelis™ (Ecteinascidin-743; ET-743) administered as an infusion over 1 h or 3 h every 21 days in patients with solid tumours," European Journal of Cancer, vol. 39, p. 1842-1851, 2003; available online August 14, 2003	
		Wollina, "Multicenter study of pegylated liposomal doxorubicin in patients with cutaneous T-cell lymphoma," Cancer 2003, 1:98(5):993-1001, published online July 24, 2003	

Examiner  
Signature

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Date  
Considered

12/15/2008